



# Use of Blending as a Method to Bring Filth Content Within Defect Action Levels: An Idea Whose Time Has Come?

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Use of Blending as a Method to Bring Filth Content Within Defect

Action Levels: An Idea Whose Time Has Come?

Submitted to Professor Peter Barton Hutt

in the Seminar on Food and Drug Law

in satisfaction of the written work requirement

Colleen A. Brennan

May 4, 1995

If you are eating right now, I urge you to read this later. There are just certain things about food that most of us would just rather not think about. Whether we like it or not, however, every single thing that we eat or drink in a day is composed in part of things we would not prefer to consume - such as rodent hairs, rodent excrement and insect wings.

This unpalatable matter, collectively referred to in regulations and for the purposes of this paper as filth, is monitored by the Food and Drug Administration (FDA) under the Food Drug and Cosmetic Act.<sup>1</sup> FDA has established defect action levels (DALs) for the amount of filth permitted in food. The DALs represent the amount of filth which FDA considers unavoidable. Periodic inspection of production facilities and testing of shipments of food are FDA's primary means of assessing compliance with DALs. Of course, FDA can not hope to reach more than a minute portion of the food supply or the factories, mills and farms which produce it. However, it is hoped that the penalty for noncompliance, seizure and condemnation of the contaminated food, with accompanying economic loss, will encourage the food industry to follow the DALs.

FDA has also established procedures for food salvage, means by which manufacturers can recondition food and manufacturing processes to eliminate contamination. One restriction on this is that food may not be blended, meaning that one lot of food which is above the required DAL can not be mixed with food below the level to bring the entire mixture into compliance. This limitation has come under increasing fire from those within the food industry, particularly with regard to filth not resulting from failure to comply with good manufacturing processes. While remaining firmly committed to its present policy, purposely declining to change existing regulations, FDA has shown flexibility on some occasions, which has only further angered those who oppose the current FDA policy.

This paper begins with a brief discussion, for illustrative purposes, of the evolution of regulations for reconditioning in the food salvage industry, and present requirements for reconditioning adulterated food. It then describes

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<sup>1</sup>21 U.S.C. 321 et. seq. [hereinafter FD&C Act].

the current FDA policy with regard to blending, and the theory behind the prohibition of this particular method of reconditioning adulterated food.

Part B shows the application of the rule against blending to individual cases. It begins with several cases in which the general rule was followed and blending was not allowed. It then describes a case in which FDA discretion to prohibit blending was questioned in the context of exports.

Part C describes a situation which occurred in the late 1970s, when corn produced in the southeastern part of the country became widely contaminated with aflatoxin, a carcinogen. FDA made an exception to the blending policy in the aflatoxin case, allowing contaminated corn to be blended with pure corn for feeding to animals. This ignited a controversy which still exists today.

Part D takes a more detailed look at the increasing controversy over the blending policy, and its effect on the perception of FDA regulations. Courts have concluded that FDA has the power to grant such exceptions, but the prospect of case by case analysis has prompted strenuous arguments for change. Some have called for an end to DALs, or at the very least some clarity as to the meaning of compliance guidelines. Others have argued that regardless of whether FDA's power to grant exceptions in individual cases may be deemed arbitrary, it may be more important to look at procedures for blending so that food will not be wasted when so many are starving around the world.

#### A. General Policies

Food is considered adulterated within the meaning of section 402(a) of the FD&C Act

(3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.<sup>2</sup>

FDA has sought to prevent food adulteration by the establishment of Current Good Manufacturing Practices (CGMP's),<sup>3</sup> including general criteria and specific regulations for particular types of food.<sup>4</sup> When CGMP's are violated, FDA also has determined and regulated the limited circumstances under which such food may be offered to the public.

#### 1. Food Salvage Code

One such set of regulations is the Model Food Salvage Code.<sup>5</sup> In a report issued in 1975, the General Accounting Office (GAO) revealed that food being distributed to the public through food salvage outlets was being processed, packaged and held under unsanitary conditions.<sup>6</sup> GAO found that food for sale

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<sup>2</sup>21 U.S.C. 342(a)(3), (4).

<sup>3</sup>21 C.F.R. 110; 51 Fed. Reg. 22458, 22476 (June 19, 1986).

<sup>4</sup>See eq. 44 Fed. Reg. 16215 (March 7, 1979) (regarding thermally processed low-acid foods packaged in hermetically sealed containers).

<sup>5</sup>Announced at 49 Fed. Reg. 31952 (August 9, 1984).

<sup>6</sup>GAO, Need for Regulating the Food Salvage Industry to Prevent Sale of Unwholesome and Misbranded Foods to the Public, No. MWD-75-64 (May 20, 1975) [hereinafter 1975 GAO Report].

in many salvage outlets was insufficiently reconditioned and/or insect infested,<sup>7</sup> or packaged in cans that were severely dented, rusted or otherwise damaged, leaking or swollen,<sup>8</sup> with misleading or missing labels.<sup>9</sup> Because GAO found that most of the food in salvage outlets is transported interstate for processing or sale, it is within the sphere of FDA regulation.<sup>10</sup>

In a subsequent report issued in 1979, GAO found that the problem remained, and reiterated its conclusion that FDA must step in to regulate these outlets.<sup>11</sup> One of GAO's criticisms of the Model State Code existing at the time of its report was that it provided little specific guidance as to reconditioning. GAO found that few states or cities surveyed had food salvage guidelines. Most states apparently concurred with GAO's conclusion that uniform regulatory controls were needed.<sup>12</sup> Recognizing that FDA lacks the resources to enforce regulations against retail establishments, and that state and local governments have primary jurisdiction over such outlets, the Code was intended to establish guidelines for the use of state and local food control agencies, who are best equipped to handle retail salvage outlets. It created uniform regulatory procedures for processing and packaging food for salvage operations, and a model law which included comprehensive enforcement mechanisms.<sup>13</sup>

GAO believed that the deplorable conditions which it found in the food salvage industry were a matter for the consideration of Congress in deliberating on matters of national hunger and nutrition.<sup>14</sup> The policy justification for specifically requiring regulation of the food salvage industry is that food from salvage outlets will most often be purchased by the urban poor, or institutions such as hospitals and nursing homes, and these consumers are entitled to the same protection and product information as those who purchase other food. GAO noted that the groups most likely to be affected by the condition of salvaged food were particularly vulnerable because they had less choice of food to eat, making it even more important that they not receive inferior and unsafe food from salvage outlets.<sup>15</sup>

## 2. Requirements for Reconditioning

FDA issued its present policy regarding the reconditioning of food considered adulterated under section 402(a)(4) of the FD&C Act, in a revised Compliance Policy Guide.<sup>16</sup> Proposals for reconditioning must include a method for determining whether contamination has occurred, and the extent and nature of any contamination which has occurred. Procedures to eliminate both the presently existing contamination, and the environmental conditions

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<sup>7</sup>Id. at 11-17; see also 44 Fed. Reg. 74921.

<sup>8</sup>Id. at 10; see also 44 Fed. Reg. 74921.

<sup>9</sup>Id. at 5-9; see also 44 Fed. Reg. 74921.

<sup>10</sup>Id. at 3; see also 44 Fed. Reg. 74921.

<sup>11</sup>GAO, Food Salvage Industry Should Be Prevented From Selling Unfit and Misbranded Food to the Public, No. HRD-79-32 (February 14, 1979).

<sup>12</sup>1975 GAO Report, *supra* note 6 at 23; see also 44 Fed. Reg. 74921 at 74922.

<sup>13</sup>Id. at 25-27; see also 44 Fed. Reg. 74921 at 74922.

<sup>14</sup>Id. at iv.

<sup>15</sup>Id. at 24.

<sup>16</sup>See 54 Fed. Reg. 32395 (August 7, 1989).

which caused it, must also be established. If the facility conditions leading to contamination can not be corrected, the food must be moved to a sanitary place before reconditioning can begin. In addition, sampling and testing may occur during and after the reconditioning process, to ensure that it is successfully completed.<sup>17</sup>

3. Natural or Unavoidable Defects and the Prohibition of Blending

Even if CGMP's are followed (and therefore section 402(a)(4) is not violated), food may still become contaminated so as to be rendered adulterated under the FD&C Act if it contains a filthy, putrid or decomposed substance or is otherwise unfit for food. Sale of such adulterated food would be prohibited under section 402(a)(3). FDA determined, however, that at low levels, such natural or unavoidable defects are not harmful. It established defect action levels (DALs), maximum levels at which regulatory action would not be sought against food produced under good manufacturing practices, the adulteration of which is the result of natural or unavoidable defect.<sup>18</sup>

Presumably, food which exceeds the DAL may be reconditioned, and corrective measures taken to improve quality controls and ensure that DALs will be met in the future. One measure which is not permitted, however, is blending such adulterated food with other food which is below the DAL, as 21 C.F.R. 110.110 goes on to provide:

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

When FDA initially proposed section 110.110(d) it received a number of comments objecting to the fact that the prohibition on blending was absolute, regardless of the fact that the contamination was natural and unavoidable, and not the result of violation of CGMP regulations.<sup>19</sup> FDA refused to modify its stance, however, and incorporated the proposed prohibition into the final rule

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<sup>17</sup>Id.

<sup>18</sup>21 C.F.R. 110.110 provides:

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement of section 402(a)(4) of the act that food not be prepared, packed or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

<sup>19</sup>51 Fed. Reg. 22458, 22474 (June 19, 1986).

without change, reasoning that the concern with blending is not just whether the resulting food would be safe, but also whether it would be considered adulterated under the FD&C Act.<sup>20</sup> FDA apparently concluded that although it had previously allowed blending under certain circumstances, these should be viewed as exceptions to a general prohibition, and such exceptions should be sought and determined on an individual basis.<sup>21</sup>

Food which is rejected because DALs are violated could certainly also become adulterated by failure to observe CGMPs, in violation of section 402(a)(4), but this would not result in the type of natural or unavoidable defect which is typically the subject of a DAL. When a food is considered contaminated because its filth content exceeds DALs, the adulteration at issue is generally a violation of section 402(a)(3), meaning that the food consists in whole or in part of a filthy, putrid or decomposed substance or is otherwise unfit for food. If this provision is interpreted literally, even food which has a level of contamination below a given DAL but which does contain some filth, could be considered adulterated. If food which is within the DAL is not to be considered adulterated, what is the difference between this food, and food which comes within the DAL after blending? In either case, the level of filth present is not harmful, meaning that the food in question is probably not otherwise unfit for food. As for the claim that the food contains some amount of a filthy, putrid or decomposed substance, this would be equally true in any case in which there is any filth at all, regardless of whether or not it has been blended to come below the DAL. Therefore, I do not see why it is necessary to conclude that food which is blended to meet a DAL should be considered adulterated under section 402(a)(3) of the FD&C Act, and for that reason to prohibit blending.

In addition, the same policy justifications which argue in favor of regulation of the food salvage industry and reconditioning plans support the belief that FDA should find some way to make blending work.<sup>22</sup> Prohibition of a method of cleansing contamination, such as blending, is potentially as costly as having no regulation at all for those who must rely at least to some extent on salvaged food. The higher food is priced, the more restricted are those with lesser income. Thus, they would become even more susceptible to harm, from food which has been secretly and illegally blended without regulation, than they would be if FDA found a way to utilize and regulate this process. Blending might be seen as just another method of reconditioning which would serve to provide a greater quantity of wholesome food at a cheaper price. Indeed, the exceptions in which FDA has allowed blending, have occurred in situations in which the destruction or diversion of the food in question would have had serious consequences for the national food supply.<sup>23</sup> However, if blending can reduce the amount of natural or unavoidable defects in food so that it would be safe for the public, would not the national food supply always benefit from the availability of that food instead of its destruction?

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<sup>20</sup>Id.

<sup>21</sup>These exceptions, and reactions to them, will be discussed further in Part C, infra.

<sup>22</sup>As described in sections A-i and A-2, supra.

<sup>23</sup>51 Fed. Reg. 22458 at 22474, supra note 19; see also Part C, infra.

B. Decisions Condemning Blended Food as Adulterated

As a general rule, courts have supported FDA in its contention that blended food is adulterated as defined by section 402(a)(3) of the FD&C Act, and therefore subject to condemnation.<sup>24</sup> However, it has also been held that when food has been offered for entry into interstate commerce, and is rejected as condemned even after an attempt has been made to remove filth and bring it in to compliance with the FD&C Act, there is no requirement that such food must be destroyed, and manufacturers may apply for its release for the purpose of export.<sup>25</sup>

1. Finding of Adulteration

In United States v. O.F. Bayer & Co., et. al.,<sup>26</sup> the controversy involved FDA's seizure of bags of coffee sweepings. The Second Circuit found that green coffee beans, which were swept up after having been spilled in the hold or on the deck of the ship in which they were transported, were adulterated because they had become blended with wood splinters, fibers, dust, and other filthy substances.<sup>27</sup> The court held that the beans were food, in spite of the fact that they were not fit for human consumption until they had been roasted, because they were still a component of an article of food. The court found that FDA's ruling in this regard was not clearly erroneous, and the decrees of condemnation should be affirmed.<sup>28</sup> Claimants contended that the beans should not be considered adulterated, because an attempt had been made to cleanse the sweepings, and the remaining contamination would be removed by roasting. However, the court concluded that the possibility that future processing might eliminate contamination did not preclude a finding of present contamination leading to condemnation.<sup>29</sup> The court also found that it did not have the statutory authority to require that FDA return the seized articles to the claimants to permit them to be exported.<sup>30</sup> Similarly, in Sugarman v. Forbraqd,<sup>31</sup> coffee sweepings from the floor of a ship were found to be adulterated, and were therefore refused admission into the country for import.<sup>32</sup>

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<sup>24</sup>See section B-i, *supra*.

<sup>25</sup>See section B-2, *supra*.

<sup>26</sup>188 F.2d 555 (2nd Cir. 1951).

<sup>27</sup>*Id.* at 557.

<sup>28</sup>*Id.*

<sup>29</sup>*Id.*

<sup>30</sup>*Id.* at 557—558.

<sup>31</sup>267 F. Supp 817(N.D. Cal. 1967); *affirmed*, 405 F.2d 1189 (9th Cir. 1969).

<sup>32</sup>The bags of sweepings were rejected under section 801 of the FD&C Act, 21 U.S.C. 381, which provides in relevant part:

(a) The Secretary of the Treasury shall deliver to the Secretary of Health, Education and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education and Welfare and have the right to introduce testimony. ... If it appears from the examination of such samples or otherwise that ... (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within

The coffee had been damaged by a fire on the ship, and the water and chemicals used to extinguish the fire.<sup>33</sup> Tests conducted by FDA on samples of the beans indicated that they were blackened, inside and out, and had a burnt, tar-like odor. When the beans were brewed, the resulting drink had a smoky flavor and was devoid of natural coffee flavor. Therefore, it was concluded that the beans could not make an acceptable drink.<sup>34</sup> After these tests, and conducting a hearing at which petitioners, who had purchased the damaged beans for salvage, could present evidence as to the admissibility of the beans or the possibility of bringing them into compliance, FDA condemned the beans as adulterated, and seized them.<sup>35</sup>

Petitioners then sought authorization to grind them for blending with other coffee. They contended that this would make them acceptable for use.<sup>36</sup> Conditional approval was granted for use of the beans for extraction of caffeine or for the production of soluble coffee, provided that FDA be allowed to examine the finished product.<sup>37</sup> However, FDA's letter to Respondent Forbragd, the contents of which were passed on to Petitioners, stated that:

the claimant's proposal to salvage this article under detention by grinding and blending it with other ground coffee is completely unacceptable, since this would amount to nothing more than diluting a legal article of food with an article which is unfit for food to make a low grade finished product.

... We doubt that a satisfactory soluble coffee can be produced.... If this coffee is to be utilized in making soluble coffee the firm should not blend this with other coffee beans to prepare the soluble coffee. The proposal to extract caffeine appears more likely to result in an acceptable finished product.<sup>38</sup>

The district court concurred with FDA's decision, noting that it was consistent with the major functions of FDA, preserving the integrity of the food supply, and protecting the consumer from the economic adulteration which occurs when less expensive ingredients are substituted or used to decrease the amount of more expensive ingredients, so that the resulting product is of inferior quality to what the consumer would expect of a product with that name.<sup>39</sup> Petitioners proposal, the court stated, substituted the burnt coffee beans, a

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such additional time as may be permitted pursuant to such regulations.

(b) ... If it appears to the Secretary of Health, Education and Welfare that an article included within the provisions of subsection (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provision of this subsection, the Secretary of Health, Education

and Welfare may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization).

<sup>33</sup>Sugarman v. Forbragd, supra note 31, at 818-819.

<sup>34</sup>Id. at 819.

<sup>35</sup>Id.

<sup>36</sup>Id. at 820.

<sup>37</sup>Id.

<sup>38</sup>Id.

<sup>39</sup>Id. at 829.



cheapened and worthless substance, for normal coffee, thereby adulterating the good beans as surely as if they were mixed with coffee grounds. The only value of the charred coffee would be to add bulk, which would allow the producers and distributors of the coffee to deceive the public, as careful blending would allow them to pass the substance off as pure coffee. Therefore, the court concluded, FDA would have been derelict in its duties had it not prevented the proposed blending.<sup>40</sup>

The district court also noted that under §381(a), FDA is directed to refuse admission of food if by examination of samples or otherwise there is the appearance of adulteration.<sup>41</sup> There is no requirement that the samples be found actually adulterated or that testimony from the hearing be relied on in the decision. The court therefore concluded that the decision as to whether the coffee beans in question should be permitted entry into the country was within the administrative discretion of FDA, and petitioners were not entitled to judicial review of this decision.<sup>42</sup> Agency discretion was supported, the court said, by the fact that import hearings are informal, in stark contrast to other types of hearings

provided for in the FD&C Act.<sup>43</sup> As FDA's decision could not be considered arbitrary and capricious given the facts of this case, the court found that it should not be overturned.<sup>44</sup>

The Ninth Circuit reviewed, and affirmed, the portion of the district court decision stating that FDA's ruling was not subject to judicial review.<sup>45</sup>

In more recent situations, FDA has continued to enforce its policies against blending, issuing warnings or bringing enforcement actions in situations in which food has become adulterated by mixture with food of less quality, or other filth. State governments have also brought actions against producers and distributors who have violated this policy.

For example, Lucky Stores, Inc. agreed to pay \$5 million in fines and restitution to settle charges brought by the state of California, alleging that an investigation revealed that Lucky had deceived customers by selling adulterated beef, mixing lower grade beef and pork into its high quality ground beef products in stores throughout the state. Although it denied any wrongdoing, Lucky also agreed to randomly test its meat to ensure that the problem would not occur again.<sup>46</sup>

Similarly, a warning letter was sent to Cohan Seafood Co., Inc., from FDA's San Francisco District, after an inspection of the company's plant was conducted in response to complaints of food poisoning after ingestion of fish processed at the plant. Among the violations uncovered in this inspection

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<sup>40</sup>Id.

<sup>41</sup>Id. at 823; see also, 21 U.S.C. §381 (§801 of FD&C Act), supra note 32.

<sup>42</sup>Id. at 824.

<sup>43</sup>Id.

<sup>44</sup>

<sup>45</sup>405 F.2d 1189 (9th Cir. 1969).

<sup>46</sup>Lucky Agrees to Pay \$5 Million in Meat Settlement.

Food Chemical News (January 31, 1994).

and related in the letter, was the fact that decomposed fish, and other fish of questionable quality were stored with good fish. The warning letter indicated that this blending of good and decomposed fish results in the adulteration of the good fish.<sup>47</sup>

FDA has recognized the need to monitor filth even in legally blended products. One example of this occurred when FDA proposed DALs for Mexican mole paste, at the request of a Mexican trade association, which noted that mole paste is made of a mixture of natural ingredients which have the potential to be contaminated with filth. Without DAL's, manufacturers are unsure as to the levels of filth which would be acceptable to FDA, and various FDA offices lack a guide for legal action which would provide consistency in that the same level of filth would lead to the same action across the various offices.<sup>48</sup>

A warning letter was sent by the Dallas District to Wrangler Feedyards do Cactus Feeders, Inc., for noncompliance with regulations for medicated feeds. Among the violations detected was that the feed mixers had not been cleaned between batches, resulting in the feed becoming adulterated.<sup>49</sup>

After a voluntary recall of some lots of certain kinds of butter blend products by Wilsey Foods, FDA expanded this recall to include all butter blend products, as these products were indeed found to be contaminated. The source of contamination was believed to be the whey used in the butter blends.<sup>50</sup>

Blending has also been prohibited when it has involved the mixture of whole-some food products which are not on the label and would not be expected by the consumer. A warning letter was issued to Uncle Ben's because its Country Inn Chicken Stock Rice was actually a mixture of rice and an enriched macaroni product, and this was not revealed by the product identity.<sup>51</sup>

## 2. questioning of FDA discretion

Carl Borschsenius Co., Inc. v. Gardner,<sup>52</sup> the court found that FDA did not have the authority under §801 of the FD&C Act (21 U.S.C. §381)<sup>53</sup> to prohibit the export and require the destruction of coffee after it had authorized the importer to attempt to bring the coffee into compliance with the FD&C Act. Some of the coffee had been damaged by contact with water. Approximately 1500 of 5000 bags in the shipment was wet, and some contained moldy coffee. The entire shipment was detained by FDA.<sup>54</sup> Upon examination, 2325 bags were found to be sound, and were released to petitioner under a partial release of the shipment. Petitioner also sought and received authorization to recondition the remainder of the shipment by skimming the coffee to remove

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<sup>47</sup>Fish Processing Plant Linked to Possible Food Poisoning. Food Chemical News (June 1, 1992).

<sup>48</sup>Defect Action Level For Mexican Mole Paste Proposed. Food Chemical News (February 22, 1993)

<sup>49</sup>Warning Letters Hit Medicated Feed GMP Deviations. Food Chemical News (June 1, 1992).

<sup>50</sup>FDA Investigating Salmonellosis Outbreak. Food Chemical News (December 2, 1991).

<sup>51</sup>Rice Product Labeling Hit In Warning Letter. Food Chemical News (June 1, 1992).

<sup>52</sup>282 F.Supp 396 (E.D.La. 1968).

<sup>53</sup>see note 32, supra.

<sup>54</sup>Id. at 397—398.

molded beans and drying it out to remove the wet beans, to attempt to bring it in to compliance with the FD&C Act. After reconditioning, 1730 bags had been made sound. Of the remainder, 1053 bags had not been reconditioned because they were too moldy to skim.<sup>55</sup>

FDA issued a release notice, stating that it would release the bags which had been made sound, as soon as petitioner destroyed the other bags. Petitioner, however, sought to recover the bags which had not been reconditioned, for export, claiming that they would have substantial commercial value in other countries in their present condition. The Acting FDA Director denied this request, stating that had petitioner's original intention been to export the entire lot without attempting to bring it into compliance, this would have been acceptable. However, as this coffee had been subjected to reconditioning, and the coffee which had sustained the most damage and could not be successfully reconditioned was at issue, this portion could not be exported.<sup>56</sup>

FDA moved to dismiss petitioner's action. One of the grounds for this motion was that the court lacks jurisdiction over the subject matter. FDA contended that it was acting within the scope of its discretionary authority under the FD&C Act.<sup>57</sup> Thus, the question was whether FDA had the discretion under §801(b) of the FD&C Act (21 U.S.C. §381(b)), to require the destruction of articles offered for import which are rejected because they can not be brought into compliance.<sup>58</sup>

The court held that FDA's decision was at variance with congressional policy as to the disposition of articles rejected for admission as set out in §801(a) of the FD&C Act (21 U.S.C. §381(a)), as well as other Acts which allowed an importer the opportunity to export goods rejected for import.<sup>59</sup> After reviewing several of these Acts, the court concluded that FDA had discretion to require destruction if the articles were of a type which it was unlawful under any circumstances to import, and therefore they were unlawfully offered for import, or if health and safety considerations required the destruction of the item.<sup>60</sup> The court went on to note that attempting to bring the articles into compliance would not render them involved in illegal import activity. Thus, the parenthetical mention of destruction in §801(b) does not limit the language of §801(a), which leaves the discretion with the consignee of the goods to export them within 90 days, after which time they may be ordered destroyed if they have not been exported.<sup>61</sup>

The only policy justification to support FDA's contention that the coffee should be destroyed, the court said, is its duty to preserve the integrity of the food supply by assuring that adulterated food does not secretly enter the national food supply, which it would argue can only be assured by requiring

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<sup>55</sup>Id. at 398.

<sup>56</sup>Id.

<sup>57</sup>Id. at 399—400.

<sup>58</sup>Id. at 400.

<sup>59</sup>Id. at 402.

<sup>60</sup>Id. at 403.

<sup>61</sup>Id. at 404.

destruction of adulterated food. However, the court said that this was not one of the purposes of §801(b).<sup>62</sup> Therefore, the court held that the refusal to release for export the coffee which had not been reconditioned, and conditioning the release of the sound coffee on the destruction of the adulterated coffee was outside the boundaries of FDA discretion.<sup>63</sup>

#### C. Exceptions to FDA's policy against blending

As has been discussed above, FDA's general policy prohibits blending. However, there have been occasional exceptions to this policy, and this has led to controversy. FDA maintains that these exceptions should be on a case by case basis, and the general policy should be unchanged. There is growing support, however, for the creation of a more specific policy, and to allow blending under certain circumstances. This section will describe one of the major deviations from the blending policy, which initiated much of the controversy which persists today. It will then discuss the ensuing controversy, which will lead into the discussion in Section D, Supra, of some of the theories and policy justifications supporting more liberal use of blending as a method of cleansing to bring food within established DALs.

##### 1. the aflatoxin exception

In the late 1970s and early 1980s, FDA twice granted an exemption to the blending policy for corn contaminated with aflatoxin. The first such occurrence was in 1978, when the exemption was granted to seven southeastern states in which heavy rains had resulted in levels of aflatoxin above DALs in as much as 40% or perhaps even more than half of the corn crop of the 1977 growing season.<sup>64</sup>

In these limited circumstances, FDA allowed the blending of corn unavoidably contaminated by levels of aflatoxin above DALs, with uncontaminated corn, provided that the contaminated corn had not been shipped in interstate commerce prior to FDA's approval of a technically feasible blending plan, that the blended corn met the relevant DAL of 20 parts per billion of aflatoxin, and that the blended corn was only used in certain animal feed, and not diverted to other uses, including feed for young or milk-producing animals, and human consumption. If contamination was found to result from inadequate drying or improper storage, it was deemed avoidable and therefore not eligible for the exemption.<sup>65</sup>

The reason for the exemption was that to prohibit the use of the contaminated corn would have a substantial adverse impact on the national food supply. Under the authority of 21 C.F.R. 609.8,<sup>66</sup> the Commissioner of FDA is permitted to allow exemptions if it is determined that the blended food is safe for consumption and that destruction or diversion of the food involved would substantially affect the national food supply. Having reviewed the evidence regarding aflatoxin in feed corn, the FDA Commissioner determined that this

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<sup>62</sup>Id.

<sup>63</sup>Id. at 405.

<sup>64</sup>See 43 Fed. Reg. 14122 (April 4, 1978).

<sup>65</sup>Id.

<sup>66</sup>issued at 42 Fed. Reg. 52822 (September 30, 1977).

limited exemption would not perceivably increase the health risk to mature poultry and swine and mature non-milk producing beef cattle to whom affected corn would be fed, nor to humans who would consume the meat of such animals. The Commissioner also determined that to continue the prohibition on blending, which would require the destruction of this food, would result in the required substantial effect. Thus, the exemption was granted.<sup>67</sup>

A similar exemption was granted in 1981 for the 1980 corn crop in North Carolina, South Carolina and Virginia, in order to prevent adverse impact on the national food supply.<sup>68</sup> Samples of corn from the affected states showed levels of aflatoxin contamination at least as severe, if not worse than, that which occurred in 1978.<sup>69</sup> The exemption was once again premised on 21 C.F.R. §509.8. As with the earlier exemptions, these states were required to develop plans for interstate shipping and blending of the contaminated corn, which would be approved by FDA, to ensure that contaminated corn would not be diverted to other uses.<sup>70</sup>

One difference between this and the earlier exemption, however, was that corn containing a level up to 100 parts per billion could be shipped in interstate commerce, to feed mature poultry, and mature non-milk producing livestock. Corn could be blended to achieve this level.<sup>71</sup> This opportunity was not presented in the earlier notice, which only allowed corn with aflatoxin up to 100 parts per billion to be used intrastate for limited purposes. FDA explained that it could not allow the higher level in interstate commerce because it could not sufficiently monitor the flow of the corn in interstate commerce to ensure that it would only be used for permissible purposes, and this presented an unreasonable risk that the corn could be used to feed dairy or very young animals, or even for human consumption.<sup>72</sup> Even the opportunity for intrastate use of the corn at 100 parts per billion level was limited under the earlier exemption, because many of the states involved were likewise unsure of their ability to monitor their use of the more contaminated corn within the state, so FDA said that blended corn with a higher level than 20 parts per billion of aflatoxin should not be used for any purpose.<sup>73</sup>

In 1980, prior to the authorization for the second period of exemption, a recourse loan program was instituted, from Commodity Credit Corporation, USDA, to provide price supports as interim financing which would enable producers of aflatoxin contaminated corn to hold the corn, so that they might have the opportunity to take advantage of the various procedures for utilization of this corn, which were still being developed at that time, including treating the corn with ammonia, or using it to make gasohol, as well as an additional pe-

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<sup>67</sup>43 Fed. Reg. 14122 (April 4, 1978), supra note 64.

<sup>68</sup>46 Fed. Reg. 7447 (January 23, 1981).

<sup>69</sup>*Id.* at 7448.

<sup>70</sup>*Id.*

<sup>71</sup>*Id.* at 7447.

<sup>72</sup>43 Fed. Reg. 14122 (April 4, 1978), supra, note 64.

<sup>73</sup>*Id.*

riod in which blending would be permitted, which eventually did occur.<sup>74</sup> The recourse loans were for a period of nine months, after which time they could be paid back with interest (if the producer had been able to make use of one of the procedures to make a profit from the corn), or the corn could be destroyed, and the producer could apply for disaster relief which could be used to pay the loan back.<sup>75</sup>

In 1982, as part of an overall reevaluation of the policies for regulating aflatoxin contamination in feed for food-producing animals, FDA announced a revised action level for aflatoxin in cottonseed meal, raising the level from 20 parts per billion to 300 parts per billion.<sup>76</sup> The specific change instituted was the result of severe aflatoxin contamination beginning with the 1980 cotton crop in the southwestern United States. In 1982, the state of Arizona had requested a grant of limited regulatory relief for a portion of its 1981 crop which was contaminated. Arizona cited the economic impact (estimated at \$10.7 million) on the state's oil mills should they not be able to market the meal for feed use. In addition, if this meal could not be marketed, the mills would be prevented from purchasing or processing cottonseed oil from the 1982 cotton crop, which could result in extremely adverse consequences for the cotton industry in the state, and the overall state economy.<sup>77</sup>

Given the previous experience with aflatoxin contamination, and the exemptions granted for contaminated corn, FDA had for some time been studying the situation in an effort to develop a regulatory policy which would be enforceable, while still protecting the quantity and quality of the food supply. Scientific information had advanced by this time indicating that feed with an aflatoxin level above 20 parts per billion was not harmful to animal safety, and would not result in harmful residues in meat and eggs from animals which ate such feed, and studies had progressed to the point that FDA felt that the action level could be set at 300 parts per billion for such animals.<sup>78</sup> FDA found that a level of 100 parts per billion in the total rations fed to livestock presents no reasonable risk to them or to the human food derived from them, and the cottonseed meal generally constituted no more than 11% of the total livestock rations, so the levels could be considerably higher and still be safe. However, because the contaminated meal could be used with other aflatoxin contaminated substances, or concentrated as a larger amount of the rations, FDA set the limits at 300 parts per billion.<sup>79</sup> The change did not extend, however, to dairy-producing animals, as studies were still in progress to determine the safety and

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<sup>74</sup>45 Fed. Reg. 63833 (September 26, 1980); 7 C.F.R. Part 1421.

<sup>75</sup>Id.

<sup>76</sup>47 Fed. Reg. 33007 (July 30, 1982).

<sup>77</sup>Id.

<sup>78</sup>In establishing the new level, FDA used the criteria of §406 of the FD&C Act (21 U.S.C. 346) and the regulations implementing it at 21 C.F.R. Part 509, requiring that contaminants be limited to the extent necessary to protect health, while taking into account that some level of contamination may be unavoidable in spite of good manufacturing practices. Thus, FDA was required, in making this decision, to balance risk with availability.

<sup>79</sup>47 Fed. Reg. 33007 (July 30, 1982), supra note 76, at 33008.

extent of aflatoxin residues which might occur in their milk.<sup>80</sup>

Problems with aflatoxin contaminated corn resurfaced in 1983, this time extending beyond the southeastern states, prompting FDA to create another exemption period, during which the regulatory policy adopted was similar to that used during the earlier crisis situations in 1978 and 1980. Corn with aflatoxin levels between 20 and 100 parts per billion could be shipped in interstate commerce, provided that state agencies implemented a control plan, approved by FDA, to assure that the contaminated corn would only be used to feed mature beef cattle, swine and poultry, and would not be diverted to use in feed for immature or dairy animals, or human consumption.<sup>81</sup> One unique feature of this plan, however, was FDA's national enforcement effort, which included sampling corn in interstate commerce, with emphasis on corn which is intended for use in corn products or on dairy farms, and on states not participating in the program. FDA also tested milk and milk products for aflatoxin as part of its enforcement effort.<sup>82</sup>

FDA noted that by channeling the contaminated corn into the safest feed uses, the exemption relieved pressure on producers on the local level to process contaminated corn into human food or to use it as feed for dairy animals. FDA therefore encouraged states to adopt similar policies and control plans for corn produced and used intrastate, and to monitor aflatoxin levels in milk, or corn intended for human food.<sup>83</sup>

In 1989, FDA issued a Revised Compliance Policy Guide, which attempted to clarify the levels of aflatoxin contamination in corn intended for use in animal feed, at which charges of adulteration might be brought under the FD&C Act.<sup>84</sup> For a case to be brought claiming adulteration under §402(a)(1) of the FD&C Act (21 U.S.C. 342), the government would have to show that there is a reasonable possibility of harm. Therefore, FDA reasoned, the action levels should be established such that FDA believes higher levels would satisfy the may render it injurious test.<sup>85</sup> FDA noted, however, that action levels should be viewed as guidelines, rather than bright line rules, as there might be cases in which the government would want to bring actions below the DALs, and other times when there might be reasons not to enforce the levels when they are violated, such as the exemptions granted for aflatoxin contaminated corn.<sup>86</sup>

The notice also contained an announcement that under its discretion as to the enforcement provisions of the FD&C Act, FDA would not object to the blending of aflatoxin contaminated corn from the 1988 harvest with noncontaminated corn to produce a mixture with a level of aflatoxin contamination which is less than the pertinent action level, provided that the blended corn was

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<sup>80</sup>Id. at 33007—33008.

<sup>81</sup>48 Fed. Reg. 53175 (November 25, 1983).

<sup>82</sup>Id.

<sup>83</sup>Id.

<sup>84</sup>54 Fed. Reg. 22622 (May 25, 1989).

<sup>85</sup>Id. at 22623; see also §402(a)(1) of the FD&C Act; 21 U.S.C. §342(a) (1).

<sup>86</sup>54 Fed. Reg. 22622 (May 25, 1989), supra note 84, at 22623.

intended to be used only for animal feed.<sup>87</sup>

The revised action levels are: 200 parts per billion aflatoxins for corn used in feed for breeding beef cattle, 200 parts per billion for corn intended for finishing swine, and 300 parts per billion for corn intended for feedlot beef cattle. The original action level of 20 parts per billion would remain for corn intended for use by humans, for corn used to make feed for immature animals or dairy animals, or for corn the intended use of which is not known. Action levels for aflatoxin in fluid milk products also remained unchanged.<sup>88</sup>

2. Response to the Aflatoxin Contamination Exemptions

In Community Nutrition Institute v. Young,<sup>89</sup> petitioners brought suit on behalf of public interest groups and consumers,<sup>90</sup> challenging FDA's regulation of contaminants in food, and most particularly aflatoxin in corn. The initial suit, filed in District Court, attacked FDA's action levels for aflatoxin in that it violated rulemaking procedures under the FD&C Act, constituted a legislative rule issued without required notice and comment procedures, and violated the FD&C Act because it allowed blending of adulterated corn with unadulterated corn.<sup>91</sup> The District Court granted summary judgment for FDA.<sup>92</sup>

On appeal, the Court of Appeals concluded that FDA was required to set formal tolerances instead of informal action levels. Thus, since the action levels were invalidated, CNI's argument that notice and comment procedures were required to be utilized in enacting it was moot, and the issue as to whether the blending allowed violated the FD&C Act, the court said, should be reevaluated on remand.<sup>93</sup>

The Supreme Court reversed and remanded, concluding that the FD&C Act was not so clear as to preclude FDA's interpretation of the Act as allowing FDA discretion to promulgate or not promulgate tolerances, and to choose to proceed by way of action levels, and that therefore FDA's view was sufficiently rational to prevent review by a court to substitute its own judgment for that of FDA.<sup>94</sup>

On remand, the Court of Appeals considered the two issues not addressed by the Supreme Court, whether notice and comment procedures were required, and whether allowing blending without enforcement was a violation of the FD&C Act. FDA argued that its action levels were interpretive rules, mere nonbinding statements of agency enforcement policy, and therefore notice and comment procedures were not required. CNI claimed, however, that the action levels restrict enforcement discretion enough to be considered legislative rules, for which notice and comment procedures would be required.<sup>95</sup>

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<sup>87</sup>54 Fed. Reg. 22622 (May 25, 1989), supra note 84.

<sup>88</sup>Id. at 22623.

<sup>89</sup>818 F.2d 943, 260 U.S.App.D.C. 294 (1987).

<sup>90</sup>hereinafter collectively referred to as CNI.

<sup>91</sup>Community Nutrition Institute v. Young, supra note 89, at 945.

<sup>92</sup>Id.

<sup>93</sup>Id. at 945; see also, 757 F.2d 354.

<sup>94</sup>Community Nutrition Institute v. Young, supra note 89, at 945; see also, 106 S.Ct. 2360.

<sup>95</sup>Community Nutrition Institute v. Young, supra note 89, at



The court identified two criteria for interpretive statements of policy, that they have no present effect and impose no rights and obligations, and that the agency and decision makers remain free to exercise discretion.<sup>96</sup> The court concluded that the action levels at issue in this case had present effect and were binding. It found support for this conclusion in the way that the action levels were described, as well as the fact that producers had to request exemptions. The fact that the action levels were not completely binding, in that FDA would still have to prove adulteration if an action were brought, and a producer would not, therefore, automatically be subject to enforcement proceedings for violation of the action level, was not sufficient to call the action levels policy statements, the court said, because they so limited agency discretion.<sup>97</sup> The court noted that FDA remained free, under the Supreme Court decision, to maintain informal tolerances. However, the substantive effect of the action levels at issue here made them impermissible. Thus, the court held that FDA action levels were legislative rules, subject to notice-and-comment requirements which had not been observed, and therefore could not be allowed to stand.<sup>98</sup>

The court also found, however, that although CNI was correct in noting that when uncontaminated corn was blended with corn contaminated with aflatoxin beyond the DAL, the resulting blend was adulterated (which FDA did not dispute), this meant only that FDA could choose to bring enforcement proceedings, not that it is required to do so. Such enforcement decisions, the court concluded, are vested with FDA. Thus, FDA could not be required to institute enforcement proceedings against food producers who created adulterated food by blending adulterated and unadulterated corn.<sup>99</sup>

#### D. Criticism of the Policy Against Blending

The theory behind the long standing policy against blending has been explored throughout this paper. It is clear that if blending were allowed, there would be increased concerns that food might be mixed with non-food substances,<sup>100</sup> or that good food could become contaminated with worthless or

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<sup>945</sup>—946.

<sup>96</sup>Id. at 946.

<sup>97</sup>Id. at 946—949.

<sup>98</sup>Id. at 949. The distinction between interpretive policy statements and substantive legislative rules has been challenged throughout the various areas of FDA discretion, as producers and manufacturers have sought notice and comment and other formal procedures. The existence of fairly recent cases would seem to indicate that this controversy has not yet been solved. See eg. *Professionals and Patients for Customized Care v. Shalala*, 847 F. Supp 1359 (S.D. Texas 1994) (compliance policy guide prescribing when manufacture adulterated or unapproved new drugs for human use at state licensed pharmacies is beyond traditional pharmacy and may be subject to enforcement action was an interpretive statement rather than a substantive rule, so notice and comment procedures were not required, and the policy was not subject to an injunction.); *Heterochemical Corp., et. al. v. FDA*, 741 F.Supp 382 (E.D.NY 1990) (where FDA published a notice initiating enforcement procedures, it was required to take mandatory enforcement steps.); *Bellarno v. FDA*, 678 F.Supp 410 (E.D.NY 1988) (FDA import alert which required that all American goods returned pharmaceuticals must be detained and reexported unless importer provided documents establishing complete chain of custody was invalidated by FDA's failure to conduct notice and comment rulemaking procedures.).

<sup>99</sup>Id. at 949—950.

<sup>100</sup>See eg. *United States v. O.F. Bayer & Co., et. al.*, *supra* notes 26—30.

even harmful food.<sup>101</sup> Thus, the continuation of the present policy prohibiting blending would appear to be consistent with FDA's purposes of preserving the integrity of the food supply and preventing economic adulteration.

1. Issues as to the National Food Supply

Other equally valid policy concerns, however, argue in favor of eliminating the absolute prohibition against blending. The most notable issue in this regard is the fact that if blending were available to reduce the presence of filth or other contamination, the food at issue could be added to the national food supply rather than destroyed. This point is shown to be relevant in light of the fact that when FDA has granted limited exemptions to the policy against blending,<sup>102</sup> the rationale behind these exemptions has been that there would be a substantial adverse impact on the food supply if the items involved were destroyed.

The argument has been made for years that a regulated policy to allow blending would have a positive effect on the food supply, and that concerns as to the availability of sufficient food at affordable prices might necessitate a reevaluation of FDA prohibition of blending.<sup>103</sup>

Hutt raises the possibility of allowing blending under certain limited circumstances. He specifically mentions animal feed as one context in which blending might be appropriate, and suggests that there might be other similarly limited circumstances in which blending could be allowed, which would result in an increase in the size of the food supply, while at the same time protecting its quality. Hutt concludes that given the status of the world population and food supply, blind adherence to the current policy against blending is not justifiable.<sup>104</sup>

McNamara likewise believes that destruction of food which violates a defect action level is becoming increasingly harder to justify, if blending could bring the lot of food below the DAL.<sup>105</sup> He particularly points to circumstances in which the contamination is unavoidable, manufacturers have utilized CGMPs, and are not at fault for the defect, and no health hazard is presented.<sup>106</sup>

2. Impact on Pesticide Policies

One specific policy area in which the potentially arbitrary nature of the system of DALs and the prohibition against blending to achieve compliance with them has become apparent is pesticide residues in food.<sup>107</sup> According to policies and regulations coordinated by FDA and EPA, tolerance levels for pesticide residues are established for raw agricultural commodities. Processed

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<sup>101</sup>see text accompanying notes 31-51, *supra*.

<sup>102</sup>as in the situations involving aflatoxin contaminated corn and cottonseed meal, discussed in Part C-i, *supra*, text accompanying notes 64-88.

<sup>103</sup>See eq. Peter Barton Hutt, The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food, 33 FDC L.J. 505 (1978); Stephen H. McNamara, Some Legal Aspects of Providing a Sufficient Food Supply for a Hungry Population, 30 FDC L.J. 527 (1975).

<sup>104</sup>Hutt, *supra* note 103, at 525.

<sup>105</sup>McNamara, *supra* note 103, at 533.

<sup>106</sup>Id. These are, of course, the conditions under which FDA authorized exemptions for aflatoxin contamination when concern with the food supply justified it.

<sup>107</sup>Edward Dunkelberger and Richard A. Merrill, *The Delaney Paradox Reexamined: Regulation Pesticides in Processed Food*, 48 Food & Drug L.J. 411 (1993).

foods made from these commodities are considered adulterated if the level of pesticides in the resulting product is higher than that allowed for the raw commodity, unless an allowance is made for the higher level.<sup>108</sup>

Because processing often tends to concentrate pesticides occurring in raw agricultural products, pesticide levels are quite likely to exceed the accepted level for the raw commodity unless the pesticide level in the raw commodity is substantially below the accepted tolerance. Dunkelberger and Merrill suggest that perhaps the response to this should be to set the tolerance levels for raw commodities sufficiently low so that the use of pesticides would have to be restricted.<sup>109</sup> Instead, they note, the approach appears to have been to set artificially high tolerance levels for processed food, to avoid the problem, but increase the risk to the public.<sup>110</sup>

Food considered adulterated by pesticides after processing can not be blended with other food to lower the pesticide level if the processed food is ready to eat, and the producers of such food will be required to declare the pesticide as a food additive and seek its inclusion as such. Controversy has continued to swirl, however, as to the meaning of ready to eat. It appears that the language was designed with the hope that very few things would be considered ready to eat.

However, Dunkelberger and Merrill argue that the emphasis of policies regarding pesticides should be on the amount of risk to the public. Whether the food in question is a raw agricultural commodity, or a processed food, the relevant inquiry should be whether the risk is more than negligible, and the bulk of the regulatory effort should be geared toward eliminating those pesticides which are most harmful and protecting against foods which contain them.<sup>111</sup> As for other pesticides, which carry less risk, allowances might be made for the concentration which occurs in processing.<sup>112</sup> This is consistent with the view of those who have advocated wider use of blending, and FDA'S position when exemptions have been created and blending has been allowed; it should only be permitted when it can be achieved without risk to the public.

### 3. Problem of Case by Case Consideration

In addition, the case by case nature of the system by which exemptions are now obtained and blending is occasionally permitted has also been a source of controversy, which has led some to question FDA'S regulatory power and discretion.<sup>113</sup>

As a result of the decision in Community Nutrition Institute  
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v. Young,<sup>114</sup> FDA proposed a rule which would make its advisory

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<sup>108</sup>See 23 Fed. Reg. 9511, 9511-12 (December 9, 1958); 24 Fed. Reg. 2434, 2434-35 (March 28, 1959) (FDA regulations implementing Food Additives Amendment).

<sup>109</sup>Dunkelberger and Merrill, supra note 103.

<sup>110</sup>Id.

<sup>111</sup>Id.

<sup>112</sup>Id.

<sup>113</sup>See eg. Community Nutrition Institute v. Young, supra note 89.

<sup>114</sup>supra note 89; see text accompanying notes 89 through 99.

opinions, guidelines and policy statements non-binding. Although such statements would remain FDA's best advice on the subject, they would no longer be considered a formal statement of FDA position, and enforcement actions contrary to these statements would be possible.<sup>115</sup>

Some commentators have expressed the belief that these statements would continue to be made and relied on anyway, and the new position would be ignored.<sup>116</sup> Kracov and Brady note that FDA's new view of these statements could decrease the amount of information available to food producers and consumers, hinder product development and lessen consistency of compliance.<sup>117</sup> They suggest adherence to policy statements and guidelines unless there is some specific reason to deviate from them, and take a hierarchical approach to the various types of guidance documents, stressing that FDA should pay particular attention to making sure that the most important and substantive of these documents will still be uniformly interpreted and applied, to decrease the potential negative effects.<sup>118</sup>

Thus, the decision as to whether a given action requires notice-and-comment rulemaking procedures, or is an interpretive rule or policy statement must be made on an individual, case by case basis. Following the decision in *Community Nutrition Institute v. Young*,<sup>119</sup> FDA will have to use notice-and-comment procedures in the future to create an exemption to the prohibition against blending. This will only make it more unwieldy for FDA to make an exemption when it believes one is necessary, and therefore make it more difficult for FDA to ensure an adequate food supply. If FDA were to change its regulations to make greater general use of blending, this decision, too, would go through notice-and-comment procedures, but at least when it was through, the policy would stand, and specific exemptions would not be needed. This is further support for the idea that blending should be considered, at least in some limited circumstances, such as those in which it has been successfully authorized by exemption in the past.

#### 4. Computerized Blending in the Future?

Finally, one indicator that blending may be even more desirable in the future is that researchers are looking at ways to accomplish blending by computer.<sup>120</sup> Thus far, computer-aided blending research has touched on such areas as the aroma of wine and juice, preventing spoilage of milk and determining the age and variety of cheese.<sup>121</sup>

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<sup>115</sup>See 57 Fed. Reg. 47,314 (Oct. 15, 1992).

<sup>116</sup>See eg. Daniel A. Kracov and Robert P. Brady, Food and Drug Administration Advisory Opinions and Guidance Documents After *Community Nutrition Institute v. Young*, 48 Food & Drug L.J. 47(1993).

<sup>117</sup>Id.

<sup>118</sup>Id.

<sup>119</sup>supra note 89.

<sup>120</sup>Computer-aided Blending Finds Wine, Juice, Cheese, Milk, Fish Applications, Emerging Food R & D Report (June 1, 1993).

<sup>121</sup>Id.

Who knows if one day they might be able to use a computer to detect filth and determine the appropriate type and amount of blending to eliminate the adulteration without risk to the consumer. Perhaps computers could even alleviate the enforcement concern most commonly raised to prevent alteration of the blending policy, by detecting covert blending, thereby allowing FDA to catch those who might attempt to take advantage of the ability to blend, to deceive the consumer with a cheaper or worthless product.

### Conclusion

It may be in the best interests of the integrity of FDA as an institution, as well as food producers and the overall food supply, to find a way to make blending work. Now, as FDA has been forced on several occasions to allow blending to avert disastrous consequences, perhaps the benefits of a wider policy of regulated blending, which have become increasingly more apparent, will be more attractive to FDA. It certainly would take a great deal of study, but it could be done.

As with the aflatoxin exemptions, FDA would first have to determine the levels at which various substances subject to blending would be harmful (presumably the DAL, which should already exist). The exceptions have shown that an approved plan for blending can be created and maintained by food producers and manufacturers, with supervisory assistance from state governments. FDA could contribute some enforcement by testing of samples, as it did during the 1989 aflatoxin exemption, and could provide for severe penalties to those who would violate approved regulations. Thus, FDA would have some means of ensuring that blending would not be abused.

FDA'S justification for its present policy has been that it must protect the consumer and the food supply, and that to allow blending would open the door to intentional adulteration to make products more cheaply. However, given the competing concerns, FDA is not really protecting either the consumer or the food supply by not allowing blending, as the food supply is in danger of being inadequate, because food is destroyed as a result of natural and unavoidable defects which could be alleviated so that they would not be harmful to the public.

The growing population produces many challenges for FDA, and FDA will undoubtedly cope with this in a variety of ways. However, it is likely only a matter of time before the policy against blending will need to be altered. It may take another crisis, such as the previous aflatoxin situations, to finally bring about the change, and of course it remains to be seen the extent to which such a change will be practicable, but it appears the time is fast approaching for serious discussion and a move toward at least some limited change in the present policy.